Complete Summary

GUIDELINE TITLE

Guidelines for oesophageal manometry and pH monitoring.

BIBLIOGRAPHIC SOURCE(S)

Bodger K, Trudgill N. Guidelines for oesophageal manometry and pH monitoring. London (UK): British Society of Gastroenterology (BSG); 2006 Nov. 11 p. [147 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Oesophageal symptoms and disorders, including

- Achalasia
- Dysphagia
- Diffuse oesophageal spasm
- Non-specific disorders of motility (e.g., nutcracker oesophagus, hypertensive lower oesophageal sphincter [LOS], hypotensive LOS)
- Gastroesophageal reflux (heartburn or acid regurgitation)
- Chest pain, throat and respiratory symptoms

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management

CLINICAL SPECIALTY

Gastroenterology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To reassess the clinical role of oesophageal manometry and ambulatory oesophageal pH monitoring in the evaluation of oesophageal symptoms

TARGET POPULATION

Patients with suspected oesophageal symptoms

Note: The application of oesophageal studies in the pediatric population is considered beyond the scope of these guidelines.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Flexible endoscopy and/or contrast radiology
2. Therapeutic trial of proton pump inhibitor (PPI) for acid reflux patients
3. Patient written consent with discussion of procedure and alternatives
4. Oesophageal manometry
    - Minimum dataset for oesophageal manometry reporting
5. Ambulatory oesophageal pH monitoring
    - Technical aspects of pH monitoring
    - Interpretation of oesophageal pH data

MAJOR OUTCOMES CONSIDERED

- Utility of oesophageal manometry for the diagnosis of oesophageal motility disorders
- Sensitivity and specificity of oesophageal pH monitoring
- Intra-subject reproducibility of oesophageal pH monitoring
- Utility of oesophageal pH monitoring for the evaluation of acid reflux symptoms
- Morbidity associated with manometry and pH monitoring procedures

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

These guidelines are based on a Medline literature search using the search terms "oesophageal manometry" and "oesophageal pH monitoring", and on expert opinion and review.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Categories of Evidence

The strength of evidence used to formulate these guidelines was graded according to the following system:

- **Ia** - Evidence obtained from meta-analysis of randomized controlled trials.
- **Ib** - Evidence obtained from at least one randomized controlled trial.
- **IIa** - Evidence obtained from at least one well designed controlled study without randomisation.
- **IIb** - Evidence obtained from at least one other type of well designed quasi experimental study.
- **III** - Evidence obtained from well designed nonexperimental descriptive studies such as comparative studies, correlation studies, and case studies.
- **IV** - Evidence obtained from expert committee reports or opinions, or clinical experiences of respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

These guidelines have been produced in accordance with recommendations of the North of England evidence based guidelines development project.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations

The strength of each recommendation is dependent on the category of evidence supporting it, and is graded according to the following system:

- **Grade A** - requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency, addressing the specific recommendation (evidence categories Ia, Ib).
- **Grade B** - requires the availability of clinical studies without randomisation on the topic of recommendation (evidence categories IIa, IIb, III).
- **Grade C** - requires evidence from expert committee reports or opinions, or clinical experience of respected authorities, in the absence of directly applicable clinical studies of good quality (evidence category IV).

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The definitions for the categories of evidence (**Ia, Ib, IIa, IIb, III, IV**) and strength of the recommendations (**grade A-C**) are provided at the end of the "Major Recommendations" field.

In patients with suspected oesophageal symptoms, flexible endoscopy and/or contrast radiology (e.g., barium swallow) should be performed before considering manometric assessment **(Evidence grade C)**.

Oesophageal manometry is indicated for the evaluation of dysphagia not definitively diagnosed by means of endoscopy and/or radiology, as manometry is the most accurate method for diagnosing the well-characterised primary oesophageal motility disorders (achalasia and diffuse oesophageal spasm) **(Evidence grade C)**.

Oesophageal manometry is the most accurate method for pH electrode placement **(Evidence grade B)**.

Acid gastro-oesophageal reflux accounts for a significant proportion of non-specific manometric abnormalities and a therapeutic trial of a proton pump inhibitor is recommended in the initial management of patients with suspected oesophageal symptoms, who have non-specific motility abnormalities identified at manometry **(Evidence grade C)**.

Pre-operative oesophageal manometry is of limited value but does prevent anti-reflux surgery in the rare patients who present with clinical features suggestive of acid gastrooesophageal reflux and have a primary motility disorder, such as achalasia, and is therefore recommended **(Evidence grade C)**.

In the absence of locally determined ranges for defining the limits of physiological acid reflux, the following data should be utilised: percentage total time oesophageal pH<4 <5%; percentage upright time oesophageal pH<4 <8%; percentage supine time oesophageal pH<4 <3%; number of episodes pH<4 for >5 minutes <3 **(Evidence grade B)**.

Ambulatory oesophageal pH monitoring has clear limitations in defining pathological acid reflux due to false negative studies, but it is the only investigation that provides information on whether patients' symptoms are related to acid reflux. The optimal period for analysis is from two minutes before to the time the event marker on the data logger was pressed **(Evidence grade B)**. A measure of the association of the patient's symptoms and acid reflux episodes, such as the symptom index, and the number of symptomatic events, should be included in the report of an ambulatory oesophageal pH study **(Evidence grade C)**.

Ambulatory oesophageal pH monitoring has no role in the initial management of patients with symptoms suggestive of acid gastro-oesophageal reflux. A high dose therapeutic trial of a proton pump inhibitor is the diagnostic investigation of choice **(Evidence grade B)**. In patients with symptoms suggestive of acid gastro-oesophageal reflux, who fail to respond during a therapeutic trial of a proton pump inhibitor, ambulatory oesophageal pH monitoring on a proton ump inhibitor may be of value to obviate the need for repeated, potentially futile, attempts at dose escalation **(Evidence grade C)**.

Chest pain, throat and respiratory symptoms may be due to acid gastro-oesophageal reflux, particularly in patients with heartburn or acid regurgitation and no alternative explanation for their symptoms. A high dose therapeutic trial of a proton pump inhibitor is indicated in such patients **(Evidence grade B)**. In patients with throat or respiratory symptoms this trial should be for four months, as a symptomatic response may be delayed **(Evidence grade B)**. Ambulatory oesophageal pH monitoring off therapy may be of value to exclude excess acid gastro-oesophageal reflux when this appears unlikely or pH monitoring on a proton pump inhibitor may be of value when there is an inadequate response to a therapeutic trial, to judge whether further dose escalation is appropriate **(Evidence grade C)**.

Patients with endoscopic oesophagitis and a good response to a proton pump inhibitor do not require an ambulatory oesophageal pH study prior to anti-reflux surgery. Patients with symptoms suggestive of acid reflux without endoscopic oesophagitis and a good response to a proton pump inhibitor should undergo

ambulatory oesophageal pH monitoring off therapy prior to anti-reflux surgery **(Evidence grade C)**. Patients with symptoms potentially due to acid reflux who fail to respond to a high dose proton pump inhibitor should undergo ambulatory oesophageal pH monitoring on a proton pump inhibitor prior to anti-reflux surgery and a good correlation between the patient's symptoms and acid reflux episodes, as assessed by the symptom index, established **(Evidence grade C)**. Ambulatory oesophageal pH monitoring should be undertaken in patients with persistent symptoms following anti-reflux surgery, particularly if further surgery is planned, to ensure there is evidence of persistent acid reflux and a good correlation between the patient's symptoms and acid reflux episodes **(Evidence grade C)**.

Oesophageal manometry and ambulatory oesophageal pH monitoring are associated with minor morbidity, largely vasovagal episodes, discomfort from the catheter and a runny nose, and restrictions affecting diet and activity. Patients with a heart valve replacement or a previous episode of bacterial endocarditis should receive antibiotic prophylaxis **(Evidence grade C)**. All patients undergoing oesophageal manometry or ambulatory oesophageal pH monitoring should give written informed consent **(Evidence grade C)**.

To ensure high clinical standards in oesophageal function testing, all clinicians undertaking oesophageal manometry or pH monitoring in the United Kingdom should be registered with the Association of Gastrointestinal Physiologists (AGIP) **(Evidence grade C)**.

Definitions:

Categories of Evidence

- **Ia** - Evidence obtained from meta-analysis of randomized controlled trials.
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- **IIb** - Evidence obtained from at least one other type of well designed quasi experimental study.
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- **IV** - Evidence obtained from expert committee reports or opinions, or clinical experiences of respected authorities.

Grading of Recommendations

- **Grade A** - requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency, addressing the specific recommendation (evidence categories Ia, Ib).
- **Grade B** - requires the availability of clinical studies without randomisation on the topic of recommendation (evidence categories IIa, IIb, III).
- **Grade C** - requires evidence from expert committee reports or opinions, or clinical experience of respected authorities, in the absence of directly applicable clinical studies of good quality (evidence category IV).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of oesophageal manometry and ambulatory pH monitoring in patients with oesophageal disorders

POTENTIAL HARMS

- Oesophageal manometry and ambulatory oesophageal pH monitoring are associated with minor morbidity, largely vasovagal episodes, discomfort from the catheter and a runny nose, and restrictions affecting diet and activity. Theoretically, intubation with a manometric catheter or pH electrode may result in trauma to the nose, pharynx, larynx or oesophagus resulting in bleeding, perforation, vocal cord injury or bronchospasm. However, the occurrence and the frequency of these events have not been documented in the published literature.
- Patients with a heart valve replacement or a previous episode of bacterial endocarditis are potentially at risk of bacteraemia during intubation. Although there are no documented cases of bacterial endocarditis following oesophageal manometry or pH monitoring, antibiotic prophylaxis, as recommended in the British Society of Gastroenterology guidelines for antibiotic prophylaxis in gastrointestinal endoscopy, should be given to such patients.

CONTRAINDICATIONS

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Contraindications to Oesophageal Manometry and pH Monitoring

Oesophageal manometry and pH monitoring should not be performed in cases of suspected or confirmed pharyngeal or upper oesophageal obstruction, in patients with severe coagulopathy (but not anticoagulation within the therapeutic range), bullous disorders of the oesophageal mucosa, cardiac conditions in which vagal stimulation is poorly tolerated, or in individuals who are not able to comply with simple instructions. Patients with peptic strictures, oesophageal ulcers, oesophageal or junctional tumours, varices or large diverticulae are at increased risk of complications from blind oesophageal intubation and such conditions are a relative contraindication to performing manometry and pH monitoring. There may be special circumstances in which manometry or pH monitoring is indicated in

certain of the above categories of patient, in which case special precautions should be considered (e.g., endoscopic or radiological guidance).

QUALIFYING STATEMENTS

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These guidelines have been prepared by the British Society of Gastroenterology. They represent a consensus of best practice based on the available evidence at the time of preparation. They may not apply in all situations and should be interpreted in the light of specific clinical situations and resource availability.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Nov

GUIDELINE DEVELOPER(S)

British Society of Gastroenterology - Medical Specialty Society

SOURCE(S) OF FUNDING

British Society of Gastroenterology

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Both of the authors have received honoraria from manufacturers of proton pump inhibitors for speaker's fees.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the British Society of Gastroenterology Web site.

Print copies: Available from Chris Romaya, British Society of Gastroenterology, 3 St Andrews Place, Regent's Park, London NW1 4LB

AVAILABILITY OF COMPANION DOCUMENTS

Suggested audit topics are available in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 17, 2009. The information was verified by the guideline developer on July 21, 2009.

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